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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------|---------------|----------------------|------------------------------|------------------|
| 09/592,034 | 06/12/2000 | Henry L. Griesbach | 03768/9312 (14014) KCX-11 | 5097 |
| 75 | 90 06/13/2003 | | | |
| Senniger, Powers, Leavitt & Roedel | | | EXAMINER | |
| One Metropolita 16th Floor | • | | THORNTON, KRISANNE MARIE | |
| St. Louis, MO 63102 | | | ART UNIT | PAPER NUMBER |
| | | | 1744 | *** |
| | | | DATE MAILED: 06/13/2003 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | |
|--|--|---|--|--|--|
| • | 09/592,034 | GRIESBACH ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | Krisanne M. Thornton | 1744 | | | |
| The MAILING DATE of this communication | | | | | |
| Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR R THE MAILING DATE OF THIS COMMUNICATI - Extensions of time may be available under the provisions of 37 C after SIX (6) MONTHS from the mailing date of this communicatio - If the period for reply specified above is less than thirty (30) days, - If NO period for reply is specified above, the maximum statutory p - Failure to reply within the set or extended period for reply will, by - Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b). Status | ON. FR 1.136(a). In no event, however, may a on. a reply within the statutory minimum of th eriod will apply and will expire SIX (6) MO statute, cause the application to become A | reply be timely filed irty (30) days will be considered timely. NTHS from the mailing date of this communication. ABANDONED (35 U.S.C.§ 133). | | | |
| 1)☐ Responsive to communication(s) filed on | · | | | | |
| 2a) ☐ This action is FINAL . 2b) ⊠ | This action is non-final. | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | |
| 4) Claim(s) <u>1-27</u> is/are pending in the applic | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | |
| 6)⊠ Claim(s) <u>1-27</u> is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) are subject to restriction a Application Papers | nd/or election requirement. | | | | |
| 9)☐ The specification is objected to by the Exa | miner. | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner. | | | | | |
| lf appro∨ed, corrected drawings are required | in reply to this Office action. | | | | |
| 12) The oath or declaration is objected to by th | e Examiner. | | | | |
| Priority under 35 U.S.C. §§ 119 and 120 | | | | | |
| 13) Acknowledgment is made of a claim for fo | reign priority under 35 U.S.C. | . § 119(a)-(d) or (f). | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | |
| 1. Certified copies of the priority docur | ments have been received. | | | | |
| 2. Certified copies of the priority docur | ments have been received in a | Application No | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| 14)[☐ Acknowledgment is made of a claim for dor | nestic priority under 35 U.S.C | . § 119(e) (to a provisional application). | | | |
| a) ☐ The translation of the foreign languag 15)☐ Acknowledgment is made of a claim for do | | | | | |
| Attachment(s) | · • | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-944) 3) Information Disclosure Statement(s) (PTO-1449) Paper No. | 3) 5) Notice of | v Summary (PTO-413) Paper No(s) f Informal Patent Application (PTO-152) | | | |
| J.S. Patent and Trademark Office PTO-326 (Rev. 04-01) Offi | ice Action Summary | Part of Paper No. 6 | | | |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "high humidity" within this claim is found to be vague and indefinite because it is unclear as to what would constitute "high".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leifheit et al., U.S. patent No. 5,126,070 in view of Wittrock U.S. patent No. 5,344,017.

Leifheit et al., teach a self-contained means for bactericidal chlorine dioxide generation and release.

Wittrock teach the known and expected use of flexible packaging means for containment of medical instruments to be sterilized, the containment means being integrally provided with indicator means for identifying the achievement of sterilization by time and/or sterilant concentration.

It would have been well within the purview of one or ordinary skill in the art to combine the self-contained chlorine dioxide generation with the known and expected indicating containment for sterilizable articles because it would provide for highly efficient sterilization while minimizing user handling and human error.

With respect to claims 17-19, it would have been well within the purview of one of ordinary skill in the art to substitute the flexible package of Wittrock with another traditional sterilization containment means including a rigid container of materials capable of withstanding chemical contact because the interchangeability of these is well

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recognized.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krisanne M. Thornton whose telephone number is 703-308-3914. The examiner can normally be reached on Mon.-Wed. 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7718 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

PRIMARY EXAMINER

June 12, 2003